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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/440,462	11/15/1999	WALID NAJIB ABOUL-HOSN	032301-047	2975

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EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/440,462

Applicant(s)

ABOUL-HOSN ET AL.

Examiner

Javier G. Blanco

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 10-18 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 10-18 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 22, 2004 has been entered.

Drawings

2. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Response to Amendment

3. Applicants' cancellation of claims 6, 8, 19-46, 48, and 49 in the reply filed on April 5, 2004 is acknowledged.

4. Applicants' filing of a certified copy of International Application PCT/US99/10871 in the reply filed on April 5, 2004 is acknowledged.

5. Applicants' cancellation of claim 9 in the reply filed on October 22, 2004 is acknowledged. Claims 1-5, 7, 10-18, and 47 remain pending in the application.

Claim Objections

6. Claims 1, 12, and 47 are objected to because of the following informalities:

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- a. Regarding claim 1, please (i) add a comma (--,--) after “right atrium” (see line 4), (ii) substitute “at least of portion” (see line 9) with --at least a portion--, and (iii) substitute “having” (see line 15) with --have--. Appropriate correction is required.
- b. Regarding claim 12, please add --or the left atrium-- after “pulmonary vein” (see line 2). Appropriate correction is required.
- c. Regarding claim 47, please (i) add a comma (--,--) after “left atrium” (see line 4), (ii) substitute “at least of portion” (see line 9) with --at least a portion--, and (iii) substitute “having” (see line 15) with --have--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5, 7, 10-17, and 47 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Aboul-Hosn (US 6,083,260 A; cited in Applicants’ IDS).

Referring to the Figures (particularly Figure 1), Aboul-Hosn discloses a system for circulating blood in a patient comprising a cannula assembly. Said cannula assembly comprises an outer cannula (outer conduit 30), an inner cannula (inner cannula 20) configured to be slidably received within the outer cannula (see Figures), and a reverse flow pump (reverse flow pump 50). The inner and outer cannulas form between them a lumen defining a first flow path. The

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inner cannula defines a second flow path. The reverse flow pump intake blood in a first direction through the first flow path, and output blood in a reverse direction through the second flow path (see entire document). The pump and cannula assembly have a combined priming volume of not greater than about 1000 ml (see column 8, line 65 to column 9, line 6; column 13, lines 38-44) especially since the entire volume of blood within the cannula system remains within the vascular system itself. Aboul-Hosn teaches drive unit 80 to control the pump's speed. With regards to the limitations of the placement of the conduits in various locations of the heart: (i) see entire document, particularly column 16, and (ii) these limitations are functional limitations of using the device. The functional recitations have not been given patentable weight because it is in narrative form. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 U.S.C. 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-5, 7, 10-18, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orejola (US 4,985,014; cited in a previous PTO-892) in view of Jarvik (US 5,376,114) and Koros et al. (US 5,167,223).

As seen in Figures 3-6, Orejola discloses a system for circulating blood in a patient (see entire document), the system comprising (i) a cannula assembly comprising an outer cannula (outer tubing 32) and an inner cannula (inner tubing 40) *sized and configured to be* (emphasis added) slidably received within the outer cannula, and (ii) a pump (pump 10). The inner and outer cannulas forming between them a lumen (shown in Figures 3-5) defining a first flow path, the inner cannula defining a second flow path and being *sized and configured* (emphasis added) to extend beyond the outer cannula (shown in Figure 3) to provide blood output at a location in a heart chamber (see column 3, lines 35-42).

Orejola does not disclose the pump as having at least a portion sized and configured for placement within a chest cavity. However, Jarvik teaches a cannula pump either as having at least a portion sized and configured for placement within a chest cavity or the pump may be located outside the chest cavity (see column 5, lines 53-64). With regards to a cannula pump having at least a portion sized and configured for placement within a chest cavity, Jarvik teaches that such pump (i) offers greater simplicity of application to the patient, (ii) reduces the resistance to blood flow of long tubes, (iii) reduces exposure to foreign materials, and (iv) eases patient management (see column 5, lines 53-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a cannula pump having at least a portion sized and configured for placement within a chest cavity, as taught by Jarvik, with the system of Orejola, in order to (i) offer greater simplicity of application to the patient, (ii) reduce the resistance to blood flow of long tubes, (iii) reduce exposure to foreign materials, and (iv) ease patient management.

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Orejola does not disclose a priming volume of not greater than about 1000 ml. However, Jarvik teaches a pump/cannula system that reduces the combined priming volume to the point that it could be essentially zero in order to aid in simplify management of heart function during the surgical procedure (see column 1, lines 58-64; column 6, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a pump/cannula system that reduces the combined priming volume to the point that it could be essentially zero, as taught by Jarvik, with the system of Orejola, in order to aid in simplify management of heart function during the surgical procedure.

Orejola does not disclose the pump as been coupled to a controller. However, Jarvik teaches a pump coupled to a microprocessor-based controller in order to regulate the flow and pressure of the blood flowing through the cannula (see column 3, lines 29-55). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a pump coupled to a controller, as taught by Jarvik, with the system of Orejola, in order to regulate the flow and pressure of the blood flowing through the cannula.

Orejola does not disclose the use of a cradle adapted to support the heart while the surgery is performed. However, Koros et al. teach a cradle (i.e., net) adapted to support the heart in order to provide better access to the heart for the surgeon (see Figure 1; column 3, lines 48-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a cradle to support the heart while performing a surgical procedure, as taught by Koros et al., with the system of Orejola, in order to provide better access to the heart for the surgeon.

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Regarding the intended use of the device (e.g., "*sized and configured to extend through an incision into the vena cava or the right atrium*", "*sized and configured to extend through an incision into the pulmonary vein or the left atrium*", etc.), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Response to Arguments

11. Applicant's arguments with respect to claims 1 and 47 have been considered but are moot in view of the new ground(s) of rejection.

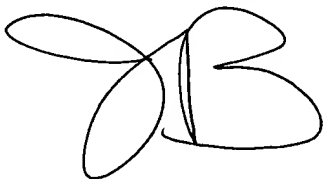
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



January 4, 2005



David H. Willse
Primary Examiner